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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,134	07/11/2003	Gerold Schuler	100725-37 / Kreisler 1108	4429

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NORRIS, MCLAUGHLIN & MARCUS, PA
875 THIRD AVENUE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,134	SCHULER ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11 and 29-34* is/are pending in the application.

4a) Of the above claim(s) *31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 10/20/06, are acknowledged.

Claim 10 has been cancelled.
Claims 9, 11, and 30 have been amended.
Claims 31-34 have been added.
Claims 9, 11, and 29-34 are pending.

2. Newly submitted claims 31-34 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention of claims 31-34 is drawn to a method of suppressing the proliferation of CD4 T cells, and requires different method steps and results in a different endpoint than the claims under examination.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 9, 11, and 29-30 are being acted upon.

3. The objection to claim 9 is withdrawn in view of Applicant's amendment to replace "energizing" with "anergizing".

4. The rejection of claim 30 under 35 U.S.C. 112 first paragraph for new matter for the recitation of cells that "inhibit" proliferation is withdrawn in view of Applicant's amendment to the claims.

5. The rejection of the claims under 35 U.S.C. 112 first paragraph for lack of written description and enablement for "anergic state inducing agents" is withdrawn in view of Applicant's amendment to the claims.

6. The rejection of the claims under 35 U.S.C. 102(a) as being anticipated by Dieckmann et al. is withdrawn in view of Applicant's submission of a declaration establishing that the Dieckmann article is describing their own work.

7. The rejection of the claims under 35 U.S.C. 102(b) as being anticipated by Thornton et al. is withdrawn in view of Applicant's amendment to the claims. Specifically, Thornton et al. do not teach a method of producing human regulatory cells.

8. The following are new grounds of rejection necessitated by Applicant's amendment

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A method for producing human Tr1-like regulatory cells comprising anergizing CD4+CD25- T cells by contacting with "CD4+CD25- T cells" (Claim 9 and dependent claims 11, and 29-30)

B) A method for producing human Tr1-like regulatory cells comprising "separating CD4+CD25+ T cells from CD4+CD25- T cells" (Claim 9 and dependent claims 11, and 29-30)

Applicant indicates that support for the new limitations can be found on pg. 3, page 5, page 9, page 14.

Regarding A), the instant specification discloses on page 3 TR1-like regulatory T cells which are obtainable by anergizing CD4+CD25- T cells by contact with CD4+CD25+ T cells, but does not disclose contact with CD4+CD25- T cells, as now claimed.

Regarding B), the instant specification discloses on pg. 3

Tr1-like regulatory T cells which are obtainable by anergizing CD3+CD25- T cells by contact with CD4+CD25+ T cells, but does not disclose the step of "separating" CD25+ T cells from CD25- T cells. The specification on page 9 discloses separating CD4+CD25+ and CD4+CD25- T cells after co-culture, and does not disclose said separation before contact, as now claimed. The specification on page 5 and 14 discloses a specific example of sorting CD4+CD25+ and CD4+CD25- T cells from the PBMC of healthy individuals followed by culturing the cells at a 1:1 ratio in vitro and stimulating with anti-CD3. The materials and methods section for Example 1 indicates that the CD4+CD25+ T cells were separated by magnetic sorting from purified CD4 populations. However, this specific example does not provide adequate support for the more generic claims, which broadly recite separating CD4+CD25+ T cells from CD4+CD25-T cells. For example, the claimed separation might encompass a crude separation based on CD25 alone, and would not require a purification of CD4 T cells, followed by separation of CD25+ T cells, as disclosed in the specific example. Furthermore, the specific example does not disclose using the separated CD4+CD25+ T cells in a method of inducing Tr1-like regulatory cells in vitro or in vivo, as recited in the instant claims.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Baecher-Allan et al., August 2001.

Baecher-Allan et al. teach a method comprising separating human CD4+CD25+ from CD4+CD25- T cells, followed by co-culturing the CD4+CD25- T cells with CD4+CD25+ T cells (see page 1246 in particular). Furthermore, the co-cultures taught by Baecher-Allan et al., would result in the contact of CD4+CD25- T cells with other CD4+CD25- T cells, as recited in claim 9. Baecher-Allan et al. also teach that the co-culture results in the inhibition of proliferation of CD4+CD25- T cells (i.e. the cells are "anergized", see page 1248 in particular). Although Baecher-Allan et al. are silent as the production of Tr1-like regulatory cells that produce IL-10, they must have inherently

obtained said regulatory cells, since they have performed the steps of the claimed method.

Thus, the reference clearly anticipates the invention.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600

12/18/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER